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10/779,892	02/17/2004	Kishore Tipirneni	40500.0117	9636

20322 7590 01/03/2007  
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EXAMINER
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BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



## DETAILED ACTION

### *Response to Amendment*

1. Applicant's amendment of claims 1, 4, 9, 11, 12, 14, 17, and 21-24 in the reply filed on May 1<sup>st</sup>, 2006 is acknowledged.
2. Applicant's addition of claims 25 and 26 in the reply filed on May 1<sup>st</sup>, 2006 is acknowledged.

### *Terminal Disclaimer*

3. The terminal disclaimer filed on February 14, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,736,819 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Election/Restrictions*

4. Applicant's election without traverse of **CAP: Species C** (embodied in Figure 2C), and **FIXATION OF BONE FRACTURE: Species G** (embodied in Figure 4G) in the reply filed on October 16, 2006 is acknowledged.
5. Claims 23, 24, and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 16, 2006.

***Drawings***

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

a. Therefore, the “spring to apply pressure to said cap” (see claim 26) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 14, "said objects" (see lines 6-7) lacks antecedent basis. Claims 15 and 16 depend on claim 14.

b. Regarding claim 15, "said object" (see line 2 and line 3) lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 3, 4, 6, 11-13, 17, 20, 21, and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fletcher (US 6,050,998 A).

Referring to Figures 1, 2, and 6-10, Fletcher discloses a system including:

(i) A head component (**first interpretation:** first/distal end of connector portion 26; **second interpretation:** first/distal barbs 28; **third interpretation:** first/distal end of connector portion 26 + first/distal barbs 28)

(ii) A wire (**first interpretation:** strand 22; **second interpretation:** second/basal end of connector 26; **third interpretation:** strand 22 + second/basal end of connector 26) having a first

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end and a second end (see column 2, lines 56-65), said wire having a first interface along at least a portion of said wire, wherein said first interface includes a sawtooth configuration (barbs 28); and

(iii) A cap (connector portion 24) having a second interface component including an inverse sawtooth configuration (internal barbs 28 of connector portion 24) on an inner surface of said cap (see column 3, lines 3-23 and lines 54-56). The excess length of wire beyond the cap is removed (see column 3, lines 23-26). A plate (plate 48) could also be included in the system (Figures 8 and 9; see column 4, lines 7-22). A tool is capable of being attached to a portion of the head component.

**NOTE:** The intended use recitations (e.g., “configured to mate”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Fletcher is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

11. Claims 11, 12, and 17-20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goble et al. (US 5,702,397 A).

Referring to Figures 6, 7, and 9-17, Goble et al. disclose a system including:

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(i) A head component (e.g., anchor 10) including a tip, cutting threads (18), and fastening threads (on the inside surface, or as part of the cutting threads on the outside surface; see column 7, lines 17-28);

(ii) A flexible wire (sutures 27) having a first end and a second end; and

(iii) A cap (e.g., plug 30), said cap *configured to mate* with said second end of said flexible wire by translating along said flexible wire over a surface (see, for example, Figure 13) which restricts (e.g., by friction, or by crimping) reverse translational movement. A tool is capable of being attached to a portion of the head component (see Figure 6). The cap includes additional openings (55).

**NOTE:** The intended use recitations (e.g., “configured to mate”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Goble et al. is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

12. Claims 14-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McLaren (US 5,100,405; previously cited in PTO-892).

Referring to Figures 1-8, McLaren discloses:

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(i) A cap device (10), said cap device having a substantially flat top surface, an outside surface, and an inside surface, said inside surface including an interface component and said outside surface including cutting threads (16, 18), said interface component including an inverse sawtooth configuration (24) on an inner surface of said cap. The cap includes additional openings (56).

The Applicants arguments (filed February 14, 2006) against McLaren '405 are based on functional and/or intended purpose limitations.

**NOTE:** The intended use recitations (e.g., “configured to mate”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by McLaren is capable of performing the recited functional and/or intended purpose limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Dally*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

13. Claims 1, 3, 4, 6, 8, 11, 12, 17, 18, 20, 21, and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cachia (US 5,893,850 A; cited in Applicant's IDS).

Referring to Figures 1-4, Cachia discloses a system including:

- (i) A head component (distal anchor 34)
- (ii) A flexible wire (pin 26: see flexible materials, thin diameters, and applications disclosed at column 5, lines 34-44; column 6, lines 16-30) having a first end and a second end, said wire



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having a first interface along at least a portion of said wire, wherein said first interface includes a sawtooth configuration (retention structure 44); and

(iii) A cap (proximal anchor 36) having a second interface component including an inverse sawtooth configuration (retention structure 42) on an inner surface of said cap (see column 4, lines 23-32 and lines 50-67). The excess length of wire beyond the cap is removed (see column 7, lines 36-40). A tensioner is used for applying tension to said wire (see entire document). A tool is capable of being attached to a portion of the head component.

**NOTE:** The intended use recitations (e.g., “configured to mate”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Cachia is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

14. Claims 11-13 and 17-21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Dakin et al. (US 6,368,326 B1; cited in Applicant’s IDS).

Referring to Figures 1-5, Dakin et al. disclose a system including:

(i) A head component (e.g., fastener 20) including a tip, cutting threads (20.4), and fastening threads (on the inside surface, or as part of the cutting threads on the outside surface);

(ii) A flexible wire (cord 22) having a first end and a second end; and

(iii) A cap (**first interpretation:** fastener 24, which has cutting threads 24.2, bore 24.3, and interior threads 24.4; **second interpretation:** locking device/screw 28, which has threads 28.1; **third interpretation:** fastener 24 + locking device/screw 28), said cap *configured to mate* with said second end of said flexible wire by translating along said flexible wire over a surface which restricts (e.g., by friction, or by crimping) reverse translational movement. A tool (e.g., driver) is capable of being attached to a portion of the head component (see entire document). A tensioner is used for applying tension to said wire (see, for example, Figure 1). A surgical plate is configured to mate with a surface of bone (see Figures).

**NOTE:** The intended use recitations (e.g., “configured to mate”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Dakin et al. is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

15. Claims 14-16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Gleason et al. (US 6,656,185 B2).

Referring to Figures 1-15 (particularly Figures 12-14), Gleason et al. disclose:

(i) A cap device (52), said cap device having a substantially flat top surface (56), an outside surface, and an inside surface, said inside surface including an interface component and said

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outside surface including cutting threads (54), said interface component including an inverse sawtooth configuration (18) on an inner surface of said cap. The cap includes additional openings (58).

**NOTE:** The intended use recitations (e.g., “configured to mate”, etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Gleason et al. is capable of performing the recited functional and/or intended purpose limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cachia (US 5,893,850 A; cited in Applicant's IDS) in view of Branch (US 5,520,691 A) and Miller et al. (US 5,423,820; previously cited in PTO-892).

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Cachia discloses the invention as claimed (see 102 (b) rejection above), except for particularly disclosing a tensioner comprising a cannulated rod having a third interface component and including a gauge. However, this is already known in the art. For example, each of Branch '691 (see Figure 16) and Miller et al. '820 (see Figure 1) discloses a tensioner comprising a cannulated rod having a third interface component and including a gauge in order to place tension on a wire while measuring the amount of tension/pulling applied to said wire. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of tensioner comprising a cannulated rod having a third interface component and including a gauge, as taught by each of Branch '691 (see Figure 16) and Miller et al. '820 (see Figure 1), with the system of Cachia, in order to place tension on a wire while measuring the amount of tension/pulling applied to said wire.

18. Claims 5, 7, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cachia (US 5,893,850 A; cited in Applicant's IDS) in view of Gleason et al. (US 6,656,185 B2).

Cachia discloses the invention as claimed (see 102 (b) rejection above), except for particularly disclosing the cap as having threads on the outside and additional openings. However, this is already known in the art. For example, Gleason et al. '185 teach a cap device (52) having an outside surface including cutting threads (54) and additional openings (58) in order to securely fasten (i.e., preventing pullout) the cap to the bone. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a cap having threads on the outside and additional openings, as taught by Gleason et al., with the system of Cachia, in order to securely fasten (i.e., preventing pullout) the cap to the bone.

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19. Claims 2 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cachia (US 5,893,850 A; cited in Applicant's IDS) in view of Dakin et al. (US 6,368,326 B1; cited in Applicant's IDS).

Cachia discloses the invention as claimed (see 102 (b) rejection above), except for particularly disclosing the head component as having a tip and cutting/fastening threads. However, this is already known in the art. For example, Dakin et al. disclose a system including a head component (e.g., fastener 20) including a tip, cutting threads (20.4), and fastening threads (on the inside surface, or as part of the cutting threads on the outside surface) in order to securely fasten the head component to bone and prevent pull out of said head component. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a system including a head component having a tip and cutting/fastening threads, as taught by Dakin et al., with the system of Cachia, in order to securely fasten the head component to bone and prevent pull out of said head component.

20. Claims 1-6, 8-10, 14, 15, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dakin et al. (US 6,368,326 B1; cited in Applicant's IDS) in view of Cachia (US 5,893,850 A; cited in Applicant's IDS).

Dakin et al. disclose the invention as claimed (see 102 (e) rejection above), except for particularly disclosing the cap as comprising an inverse sawtooth configuration on an inner surface (e.g., bore). However, this is already known in the art. For example, Cachia discloses (see 102(b) rejection above) a system comprising a cap/wire connection wherein the wire comprises a sawtooth configuration (retention structure 44) along at least a portion of said wire, and the cap comprises an inverse sawtooth configuration (retention structure 42) on an inner

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surface of said cap (see column 4, lines 23-32 and lines 50-67) in order to provide resistance to movement of the cap in the proximal direction relative to the wire (see column 4, lines 23-32 and lines 50-67). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a system comprising a cap/wire connection wherein the wire comprises a sawtooth configuration along at least a portion of said wire, and the cap comprises an inverse sawtooth configuration on an inner surface of said cap, as taught by Cachia, with the system of Dakin et al., in order to provide resistance to movement of the cap in the proximal direction relative to the wire.

### ***Response to Arguments***

21. Applicant's arguments with respect to claims 1, 11, 14, and 17 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

December 17, 2006



David H. Willse  
Primary Examiner